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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,346

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,346	Applicant(s) FRAHLING ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,10,15-20 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,10,15-20 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>22 Jun 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Amendments and Remarks filed, filed 29 July 2009, in the matter of Application N° 10/531,346. Said filings are entered on the record. The Examiner further acknowledges the following:

Claim 23 is newly added. Sufficient support for the new claim is provided in the originally and previously presented claims (e.g. claim 20).

Claims 21-22 are newly cancelled.

Claims 1, 6, 10 and 16-20 have been amended. Claims 1, 6 and 17-20 have been amended to indicate that the solid article is "porous", a property which is supported by Applicants disclosure (see pg. 17, lines 18-21).

Claim 1 has been further amended to recite "an aqueous solution comprising water" rather than "an aqueous solution". The Examiner's interpretation of this limitation does not change despite the amendment, particularly since it is the position of the Examiner that an "aqueous" solution would inherently comprise water.

Amendments to claims 10 and 16 concern further limiting the scope of the aqueous solution applied in step (b.) of the method of claim 1, such that the aqueous solution further comprises auxiliary substances such as pH-adjusting agents, buffering agents and stabilizers. Support for the content-related amendments is also found within the Applicants' instant disclosure (pg. 13, lines 28-32).

No new matter has been added.

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Thus, claims 1, 4-6, 10, 15-20 and 23 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

One Information Disclosure Statement (IDS), filed 22 June 2009, is acknowledged and has been considered.

WITHDRAWN OBJECTIONS/REJECTIONS

Rejections under 35 USC 112

Applicant's amendments to claims 1, 10 and 16 are sufficient enough to render moot the indefiniteness rejections under 35 USC 112, second paragraph. Thus, said rejections have been **withdrawn**.

However, it should be noted that, for the purposes of examination on the merits and despite the forgoing amendments, the Examiner continues to interpret the limitations of an "aqueous solution" comprising "pharmaceutically active", "cosmetically active", or "auxiliary", as broadly as water (e.g. tap water).

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Correspondence dated 29 April 2009 since either the grounds or art on which they were previously set forth continues to read on the amended limitations.

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CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6, 10 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kojima (US Pre-Grant Publication N° 2002/0068683).

The instant claim 1 is directed to a method of using a shaped article to apply at least one skeleton-forming agent to an external skin or hair surface of a human or animal comprising (1)

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providing a sized and shaped article, free of protein-based scaffolding agent, (2) disintegrate said article with an aqueous solution to form a solution or a gel, and (3) applying the composition to the intended surface. With regard to the limitations recited in claim 1, which state that the shaped article has been “molded [and] freeze-dried”; said limitations are deemed by the Examiner as reciting product-by-process limitations, which per MPEP §2113 hold no patentable weight. Said shaped article is further claimed as having a volume ranging from 100 microliters to 6 mL and a diameter ranging from 3-60 mm. The skeleton-forming agent recited in claim 1, is further recited as comprising at least one polysaccharide such as sodium alginate (claims 4 and 5). Claim 6 recites the article as sphere-shaped prior to contact with water (claim 6). The limitation recited within the amended claim 10, states that “the shaped article is contacted with an aqueous solution comprising one selected from the group consisting of active substances or auxiliary substances”. Claim 15 further limits the “active substance” to either a “cosmetic active substance” or a pharmaceutical active substance. Claim 16 further limits the auxiliary substance to compounds such as pH-adjusting agents, buffering substances, plasticizers and lubricants. Claims 21 and 22, which depend from claims 17 and 21 respectively, recite the same limitations as claims 10 and 15, respectively. Herein, and for the purposes of examination on the merits, despite the amendment to claim 1, the Examiner continues to interpret the recitation of an “aqueous solution” in claims 10, 15, 16, 21 and 22, as “contacting the shaped article with water (e.g. tap water)”. The shaped article is recited as further comprising one or more cosmetic or pharmaceutically active substances (claims 17 and 18) or one or more auxiliary substances such as squalane (claims 17-20).

The Abstract to Kojima teaches a shaped, water-soluble solid composition that produces a lubricating liquid when dissolved in water. The composition is also hand-held, able to be

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moistened and then applied to dry skin as a liquefied lubricant. The instantly claimed shape limitations are taught, such that the composition may be sphere-shaped (see Abstract and Fig. 6F) as well as varied in size or dimension. Test Examples 1 and 2, for instance, teach the composition as being compressed and molded from a 30-mm cube into a shape (e.g. column) having a 12-mm diameter. Based on this teaching, a molded sphere, having a 12-mm diameter an approximate volume of 905 microliters (i.e. $V_{sp} = (4/3)\pi r^3$) is conceivable, thereby teaching the limitations of the instant claims 1 and 6. The limitations of claims 4 and 5 are taught such that the composition comprises a “solidifying agent” (claim 4), which is further defined as comprising sodium alginate ¶[0018]. The limitations of claims 17-20 are taught, such that the composition may contain one or more auxiliary substances or additives (Abstract; claim 1, and ¶¶[0024] and [0038]) as well as active substances such as antiseptics ¶[0024]. Paragraph [0039] teaches the use of additives such as squalane. The limitations of claims 10, 15, 16, 21 and 22 are taught such that the solid, shaped composition is contacted with an aqueous solution such as water prior to or concurrent with application of the composition to the skin.

RESPONSE TO ARGUMENTS

Applicants’ arguments and amendments made in response to the rejection of claims 1, 4-6, 10 and 15-20 under 35 USC 103(a) as being unpatentable over the teachings of Kojima et al. have been fully considered but they are not persuasive.

Applicants argue that the rejection is overcome on the basis of the “porous” amendment alone owing to the allegation that Kojima fails to teach or suggest that a porous article is made or used.

In response, the Examiner respectfully disagrees and submits that the teachings of Kojima

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are directed to a solid medicated object which may be dissolved via lubrication with an aqueous solution such as water or tap water (e.g. consumer usage). Given that the solid object is brought into contact with water for the purpose of applying a medicament to the skin, it stands to reason that in order for the lubricating effect to occur, water must be taken up into the solid object in order for said object to begin dissolving. That being said, it is the position of the Examiner that the solid object has a porosity characteristic unto itself which allows for the natural intercalation of water between the sodium alginate molecules, thereby allowing it to breakdown and achieve the instantly claimed solution or gel form which is applied via contacting the skin. It is thus the position of the Examiner that solid lubricating object of Kojima teaches if not, minimally suggests Applicants' amended "porous" article limitation.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained** as well as extended to new claim 23.

All claims under consideration remain rejected; no claims are allowed.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615